Notice of Allowability	Application No.	Applicant(s)	
	10/663,353	LISONBEE ET AL.	
	Examiner	Art Unit	
	Jean C. Witz	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to _____.

2. ☒ The allowed claim(s) is/are *39-52*.

3. ☒ The drawings filed on *15 September 2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-38, drawn to compositions comprising transfer factor compositions, method of making transfer factor compositions and method of enhancing or elicting a T-cell mediated response, classified in class 424, subclass 581.

   II. Claims 39-45, drawn to a method of reducing the cleaning frequency of processing equipment for capsulating an egg-derived product, classified in class 424, subclass 535.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects and there is no disclosure that the inventions of Group I are capsulated.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Brick Power on September 21, 2004, an election was made without traverse to prosecute the invention of Group II, claims 39-45.

Claims 1-38 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Examiner's Amendment

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Brick Power on September 21, 2004.

The application has been amended as follows:

IN THE SPECIFICATION:

Paragraph **[0008]** has been amended to read as follows:

[0008] Antibodies, which make up only a part of the noncellular component of an immune system, recognize specific antigens and, thus, are said to be "antigen-specific." The generated antibodies then basically assist the white blood cells in locating and eliminating the pathogen from the body. Typically, once a white blood cell has generated an antibody against a pathogen, the white blood cell and all of its progenitors continue to produce the antibody. After an infection is eliminated, a small number of T-

cells and B-cells that correspond to the recognized antigens are retained in a "resting" state. When the corresponding pathogenic or antigenic agents again infect the host, the "resting" T-cells and B-cells activate and, within about forty-eight (48) hours, induce a rapid immune response. By responding in this manner, the immune system mounts a secondary immune response to a pathogen; the immune system is said to have a "memory" for that pathogen.

Paragraph **[0011]** has been amended to read as follows:

[0011] Additionally, it is believed that antigen-specific and pathogen-specific transfer factors may cause a host to elicit a delayed-type hypersensitivity immune response to pathogens or antigens for which such transfer factor molecules are not specific. Transfer factor "draws" at least the non-specific T-cells, the T-inducer and the T-suppressor cells, to an infecting pathogen or antigenic agent to facilitate a secondary, or delayed-type hypersensitivity, immune response to the infecting pathogen or antigenic agent.

Paragraph **[0021]** has been amended to read as follows:

[0021] It is also known that transfer factor may be obtained from eggs. U.S. Patent 6,468,534 to Hennen et al. (hereinafter "Hennen") describes a process by which female chickens (*i.e.,* hens) are exposed to one or more antigens, which results in the elicitation of an immune response, including a secondary immune response, by the chickens. As a result of the secondary immune response, transfer factor molecules are present in the eggs of the chicken. The eggs may then be processed to provide a product in which the transfer factor is present. Such a product may take the form of a freeze-dried, or lyophilized, egg powder, and may include all or part of the egg. The egg powder may then be incorporated directly into gelatin capsules or mixed with other substances, then introduced into gelatin capsules.

Paragraph **[0029]** has been amended to read as follows:

[0029] In another aspect, the present invention includes a method for capsulating an egg-derived product which includes transfer factor. The inventive capsulation method includes mixing a substantially fat-free component, such as a colostrum-derived product, which may or may not include transfer factor, with the egg-derived product before or while the egg-derived product is being introduced into capsulation equipment.

Paragraph **[0030]** has been amended to read as follows:

[0030] Additionally, the present invention includes a method for reducing the cleaning frequency of capsulation equipment used for capsulating an egg-derived product. That method includes mixing a less fatty or substantially fat-free substance, such as a colostrum-derived product, with the egg-derived product before or during introduction of the egg-derived product into the capsulation equipment.

Paragraph **[0037]** has been amended to read as follows:

[0037] The different types of transfer factor of the inventive composition may be obtained from any suitable source. For example, mammalian transfer factor may be obtained from colostrum, as described in Wilson, the disclosure of which is hereby incorporated herein in its entirety by this reference, or otherwise, as known in the art (*e.g.,* a leukocyte (white blood cell) extract, a splenic (*i.e.,* "from the spleen") extract, etc.). An exemplary source for nonmammalian transfer factor is an egg of an animal, such as a chicken, as described in Hennen, the disclosure of which is hereby incorporated herein in its entirety by this reference. Thus, a composition according to the present invention may include a first component which comprises a colostrum-derived product, as well as a second component that comprises egg-derived product.

Paragraph **[0040]** has been amended to read as follows:

[0040] A composition of the present invention may include about the same amounts, measured in terms of weight or volume, of a colostrum-derived product and

an egg-derived product (*i.e.,* about 50% colostrum-derived product and about 50% egg-derived product). Alternatively, a composition that incorporates teachings of the present invention may include more colostrum-derived product (*e.g.,* about 85% or 60%, by combined weight of the colostrum-derived product and egg-derived product) than egg-derived product (about 15% or 40%, by weight). As another alternative, the inventive composition may include more egg-derived product (*e.g.,* about 60% or 85%, by weight) than colostrum-derived product (*e.g.,* about 40% or 15% by weight). As another example, a composition that incorporates teachings of the present invention may include about one percent, by weight, of one of a colostrum-derived product and an egg-derived product and about 99%, by weight, of the other of the colostrum-derived product and the egg-derived product. Although specific amounts of colostrum-derived product and egg-derived product have been provided, any combination thereof is within the scope of the present invention.

Paragraph **[0041]** has been amended to read as follows:

[0041] In addition to including a source of transfer factor (*e.g.,* a colostrum-derived product, an egg-derived product, etc.), a composition that incorporates teachings of the present invention may include one or more other ingredients, including, but not limited to, vitamins, minerals, proteins, natural products (*e.g.,* herbs, mushrooms, roots, etc., or extracts thereof), and the like. Additional ingredients may be useful for providing further advantages to subjects to which the composition is administered, or may enhance the ability of the transfer factor in the composition to elicit or enhance a secondary, or delayed-type hypersensitivity, immune response.

Paragraph **[0044]** has been amended to read as follows:

[0044] Turning again to FIG. 2, a process for forming composition-filled capsules 14, such as that shown in FIG. 1, is provided merely as an example for a method for making a composition that incorporates teachings of the present invention. As illustrated, the composition 10 is made and composition-filled capsules 14 are formed using standard capsulation equipment 20 of a type known in the industry, such as the SF-135 capsule-filling machine available from CapPlus Technologies of Phoenix, Arizona.

Paragraph **[0046]** has been amended to read as follows:

[0046] As the capsulation equipment will introduce the mixture into capsules, which may be swallowed by a subject, it is currently preferred that the substantially fat-free component and the egg-derived product be introduced into the capsulation equipment in powdered form. The substantially fat-free component dilutes the amount, or concentration, of fat (*e.g.,* from egg yolk) present in the mixture relative to the concentration of fat which is present in the egg-derived product. Accordingly, the relative amounts of the substantially fat-free product and the egg-derived product may be tailored to provide a fat concentration that will minimize clogging of the capsulation equipment.

Paragraph **[0048]** has been amended to read as follows:

[0048] Following introduction of a predetermined amount of composition 10 into capsule bodies 12a at feed station 28, the filled capsule bodies 12a are transported to a capsule closing station 34, where capsule caps 12b are assembled therewith to fully contain composition 10 within capsule 12.

Paragraph **[0049]** has been amended to read as follows:

[0049] Again, a composition-filled capsule 14 is only one example of the manner in which a composition that incorporates teachings of the present invention may be embodied. The inventive composition may also take other forms, such as tablets,

caplets, loose powder, liquid, gel, liquid-filled or gel-filled capsules, or any other pharmaceutically acceptable form known in the art, each of which may be made by known processes.

Paragraph **[0050]** has been amended to read as follows:

[0050] The composition of the present invention may be administered to a subject (*e.g.,* a mammal, such as a human, a dog, or a cat, a bird, a reptile, a fish, etc.) by any suitable process (*e.g.,* enterally, parenterally, etc.), depending, of course, upon the form thereof. For example, virtually any form of the composition (*e.g.,* a capsule, tablet, caplet, powder, liquid, gel, etc.) may be administered orally (*i.e.,* through the mouth of the subject), provided that the composition includes a pharmaceutically acceptable carrier of a type known in the art that will prevent degradation or destruction of transfer factor molecules by the conditions that persist in the digestive tract of the subject without substantially interfering with the efficacy of the transfer factor molecules included in the composition.

Paragraph **[0053]** has been amended to read as follows:

[0053] The following EXAMPLES illustrate the enhanced ability of a composition which includes transfer factor from multiple types of source animals to cause an immune system of a treated subject to elicit a T-cell mediated immune response to various types of pathogens, in the form of target cells. The target cells included bacteria (*e.g., C. pneumoniae and H. pylori*) and viruses (*e.g.,* herpes simplex virus-1 (HSV-1) and herpes simplex virus-2 (HSV-2)) in the form of virally infected cells, as well as to cancerous, or malignant, cells (*e.g.,* K562 erythroleukemic cells).

IN THE CLAIMS:

Claim 39 has been amended to read:

39. (Original) A method for reducing the cleaning frequency of processing equipment used for capsulating an egg-derived product, comprising:

combining a colostrum-derived product with an egg-derived product before or during introduction of the egg-derived product into the capsulation equipment.

The following new claims have been added:

46. (New) A method for reducing the cleaning frequency of equipment used for processing an egg-derived product, comprising:
combining a colostrum-derived product with an egg-derived product before or during introduction of the egg-derived product into the equipment.

47. (New) The method of claim 46, wherein said combining comprises combining about equal weights of said colostrum-derived product and the egg-derived product.

48. (New) The method of claim 46, wherein said combining comprises combining said colostrum-derived product in a greater amount, by weight, than the egg-derived product with the egg-derived product.

49. (New) The method of claim 46, wherein said combining comprises combining said colostrum-derived product, in a lesser amount, by weight, than the egg-derived product with the egg-derived product.

50. (New) The method of claim 46, further comprising:
defatting the egg-derived product.

51. (New) The method of claim 46, further comprising:
combining at least one vitamin with at least one of the egg-derived product and said colostrum-derived product.

52. (New) The method of claim 46, wherein said combining comprises combining said colostrum-derived product and the egg-derived product with at least one of said colostrum-derived product and the egg-derived product including transfer factor.

2. This application is in condition for allowance except for the presence of claims 1-38, drawn to the invention of Group I, non-elected without traverse. Accordingly, claims 1-38 have been cancelled without prejudice to the filing of a divisional application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jean C. Witz whose telephone number is (571) 272-0927. The examiner can normally be reached on 6:30 a.m. to 4:00 p.m. M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jean C. Witz
Primary Examiner
Art Unit 1651